

**ASSEMBLY BILL**

**No. 52**

---

**Introduced by Assembly Member Portantino**

December 2, 2008

---

An act to amend Sections 1627, 1628, and 1630 of, and to add Sections 1627.5 and 1627.7 to, the Health and Safety Code, relating to umbilical cord blood banking.

LEGISLATIVE COUNSEL'S DIGEST

AB 52, as introduced, Portantino. Umbilical Cord Blood Collection Program.

Existing law requires the State Department of Public Health to establish, by January 1, 2010, and until January 1, 2015, the Umbilical Cord Blood Collection Program for the purpose of increasing the amount of umbilical cord blood that is donated in the state and that will be added to the national inventory. Existing law authorizes the department, to the extent private or public funds are identified for this purpose, to contract with blood banks that are licensed or accredited to provide umbilical cord blood banking storage services, for the purpose of collecting and storing umbilical cord blood.

This bill would, instead, require the department to establish the Umbilical Cord Blood Collection Program from January 1, 2011, until January 1, 2020, for the purpose of collecting and storing umbilical cord blood for public use, as defined, for human transplantation and human research. The bill would require the department to contract with up to 5 entities, including blood banks that are licensed or accredited to provide umbilical cord blood banking storage services, to collect, and make available for transplant or medical research, umbilical cord blood.

The bill would also establish an implementing committee composed of specified members to develop policy recommendations for purposes of implementing the program.

The bill would require the department, in consultation with the implementing committee, to submit to the Governor and specified committees of the Legislature, 2 reports on the effectiveness of the program by January 1, 2013, and January 1, 2018, respectively, and would require the program to conclude no later than December 31, 2019.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. The Legislature finds and declares all of the  
2 following:

3 (a) The umbilical cord and placenta are discarded as medical  
4 waste in a large majority of American births. However, the blood  
5 retrieved from the umbilical cord is rich in stem cells known as  
6 hematopoietic progenitor cells (HPCs) and can be used today to  
7 treat nine disorders and diseases. Clinical trials, which are currently  
8 at various stages, may reveal that umbilical cord blood could be  
9 used to treat many other disorders and diseases. These disorders  
10 and diseases include: (1) blood cancers such as leukemia, myeloma,  
11 and lymphoma; (2) immunodeficiencies and genetic diseases,  
12 including sickle cell anemia, thalassemia, inherited marrow failure  
13 disorders; and (3) inherited disorders or errors of metabolisms.

14 (b) Umbilical cord blood has been used in about 8,000  
15 transplants since 1988 and has many benefits over bone marrow.  
16 The donation procedure, conducted after birth, is painless, quick,  
17 and risk free for the mother and newborn baby.

18 (c) The National Marrow Donor Program has the largest registry  
19 in the United States that can be searched for a marrow or umbilical  
20 cord blood match when stem cell transplants are needed. In order  
21 to find the best tissue match for optimal transplant outcome, genetic  
22 diversity is needed since a patient's most likely match is someone  
23 of the same heritage. According to the National Marrow Donor  
24 Program, over 10,000 children and adults in the United States  
25 would benefit from a transplant from someone unrelated to them,

1 but only 25 percent actually receive one. This is, in part, due to  
2 the lack of acceptable stem cell source.

3 (d) Finding a marrow or blood donor match is challenging for  
4 people of all races. Only 30 percent of patients in need of a marrow  
5 or an umbilical cord blood transplant find a matched donor in their  
6 family. The other 70 percent search registries for an unrelated  
7 donor or umbilical cord blood units. Finding a match is particularly  
8 difficult for people of color, including people of multiracial  
9 ancestry, because they are underrepresented in the national  
10 inventory. Many of these patients die while waiting for a transplant.

11 (e) Because most national health and medical organizations do  
12 not recommend private umbilical cord blood banking unless there  
13 are known health reasons, it is not the intent of the Legislature to  
14 collect umbilical cord blood for private use.

15 (f) The Institute of Medicine of the National Academies' report  
16 "Cord Blood: Establishing a National Hematopoietic Stem Cell  
17 Bank Program (2005)" calls for an increase in the volume and  
18 genetic diversity of umbilical cord blood public bank inventory.  
19 This report was the basis for establishing the national Stem Cell  
20 Therapeutic and Research Act of 2005 which provides for the  
21 collection and maintenance of human umbilical cord blood stem  
22 cells for the treatment of patients and research. This act dedicated  
23 funds for this purpose.

24 (g) California has been a leader in umbilical cord blood  
25 transplant research through a number of previous projects including  
26 a sibling donor pilot project, through participation in the national  
27 study, and its current involvement in the national cord blood  
28 program.

29 (h) The national cord blood program has a goal of collecting  
30 150,000 genetically diverse units in order to increase the best  
31 chances of tissue matches. Due to a low supply of ethnically diverse  
32 umbilical cord blood they have specified target collection goals  
33 for specific ethnicities, including, but not limited to, Native  
34 American, Latino, African American, and Asian populations, and  
35 persons of multiracial ethnicities.

36 (i) California is uniquely situated to add volumes of genetically  
37 diverse, high-quality umbilical cord blood units for public banking  
38 because of its high birth rate of more than 550,000 births per year  
39 and ethnically diverse population. This contribution will not only  
40 serve the health needs of California constituents, but can contribute

1 to the national and international umbilical cord blood inventory  
2 efforts.

3 (j) An increase in stem cell transplants is also cost effective. It  
4 will save the state, insurers, donors, and patients significant moneys  
5 now being spent on lifetime medical treatments and relieve ongoing  
6 pain and anguish of affected patients and their families.

7 SEC. 2. Section 1627 of the Health and Safety Code is amended  
8 to read:

9 1627. (a) (1) On or before January 1, ~~2010~~ 2011, the State  
10 Department of Public Health shall establish the Umbilical Cord  
11 Blood Collection Program (*hereafter program*) for the purpose of  
12 ~~increasing the inventory of umbilical cord blood donated from~~  
13 ~~Californians which will be part of the national umbilical cord blood~~  
14 ~~inventory. Units collected shall be entered into a national registry~~  
15 ~~and made available to the public for purposes of human stem cell~~  
16 ~~transplant. Units collected but unusable for transplant may be made~~  
17 ~~available for research to further the understanding of the use of~~  
18 ~~umbilical cord blood as tissue to treat human diseases collecting~~  
19 ~~and storing umbilical cord blood for public use for human~~  
20 ~~transplantation and human research. The program shall conclude~~  
21 ~~no later than December 31, 2019.~~

22 ~~(b) When umbilical cord blood is used for research, research~~  
23 ~~protocols shall be approved by the Committee for the Protection~~  
24 ~~of Human Subjects or an institutional review board, as defined in~~  
25 ~~subdivision (e) of Section 125330.~~

26 ~~(c) All blood collected for either transplant or research shall~~  
27 ~~follow all applicable law and guidelines applicable to donor~~  
28 ~~confidentiality and security of donor information. All information~~  
29 ~~collected shall be confidential and shall be used solely for the~~  
30 ~~purposes of the program.~~

31 (2) For purposes of this article, “public use” means both of the  
32 following:

33 (A) The collection of an inventory of genetically diverse  
34 umbilical cord blood, for placement in the National Cord Blood  
35 Inventory Registry, to increase the likelihood of a patient obtaining  
36 a suitable donor match.

37 (B) The use of research protocols approved by the Committee  
38 for the Protection of Human Subjects or an institutional review  
39 board, as defined in subdivision (e) of Section 125330, to further

1 *the understanding of the use of umbilical cord blood as tissue to*  
2 *treat human diseases.*

3 *(b) In implementing this program, the department shall consider*  
4 *the policy recommendations of the implementing committee*  
5 *established pursuant to Section 1627.5.*

6 *(c) (1) In order to implement the program, the department shall*  
7 *contract with up to five entities, including entities that are licensed*  
8 *or accredited to provide umbilical cord blood collection and data*  
9 *processing services, and entities that provide umbilical cord blood*  
10 *banking storage services that are licensed or accredited pursuant*  
11 *to Section 1604.6, to build an inventory of anonymous umbilical*  
12 *cord blood units and make the inventory available for transplant*  
13 *or medical research for purposes consistent with the public use,*  
14 *as defined in paragraph (2) of subdivision (a). The department*  
15 *shall ensure that any cord blood bank receiving funds through the*  
16 *program also meets the federal requirements outlined in the C.W.*  
17 *Bill Young Cellular Transplantation Program (42 U.S.C. Sec. 274k*  
18 *et seq.) so that all umbilical cord blood units collected can be*  
19 *listed through the National Cord Blood Inventory Registry. A*  
20 *medical provider or research facility shall comply with, and shall*  
21 *be subject to existing penalties for violations of, all state and*  
22 *federal laws with respect to the protection of any medical*  
23 *information, as defined in subdivision (g) of Section 56.05 of the*  
24 *Civil Code, and any personally identifiable information contained*  
25 *in the umbilical cord blood inventory.*

26 *(2) In selecting qualified entities under this subdivision, the*  
27 *following shall apply:*

28 *(A) The department may use a competitive process to identify*  
29 *qualified entities to administer the program.*

30 *(B) In order to qualify for selection under this section, an entity*  
31 *shall have experience in blood collection, labeling, storage,*  
32 *transportation, or distribution. The department shall select entities*  
33 *with demonstrated ability to retrieve umbilical cord blood from*  
34 *ethnically diverse communities.*

35 *(d) The program shall attempt to meet at least all of the*  
36 *following objectives:*

37 *(1) Define and identify qualified umbilical cord blood collection*  
38 *entities.*

1     (2) *Design a competitive process to identify qualified*  
2 *participants licensed or accredited to harvest umbilical cord blood*  
3 *in a manner that complies with state and federal regulations.*

4     (3) *Establish criteria for determining which units of umbilical*  
5 *cord blood may be used for research versus transplantation, and*  
6 *policy addressing circumstances under which umbilical cord blood*  
7 *may be used for either purpose.*

8     (4) *Create collection targets for ethnically diverse populations*  
9 *in accordance with identified deficiencies in inventories.*

10    (5) *Consider a medical contingency response program to*  
11 *prepare for and respond effectively to biological, chemical, or*  
12 *radiological attacks, and other public health emergencies requiring*  
13 *treatment with umbilical cord blood.*

14    (6) *Develop a public awareness campaign that includes, but is*  
15 *not limited to, activities described in Section 123370.*

16    (7) *Increase hospital participation in collection and storage*  
17 *efforts, and identify funding sources to offset the financial impact*  
18 *on hospitals.*

19    (8) *Determine whether the program will require training of*  
20 *health care providers relative to handling, labeling, transporting,*  
21 *and storing umbilical cord blood.*

22    (9) *Determine policy on obtaining patient consent and timing*  
23 *of consent in relation to existing law and standards of care.*

24    (10) *Determine whether current law and guidelines applicable*  
25 *to donor confidentiality and security of donor information are*  
26 *sufficient and, if they are insufficient, what additional requirements*  
27 *or guidelines are necessary.*

28    (11) *Determine whether a sibling donor component would help*  
29 *achieve the overall inventory goals of the program.*

30    (12) *Explore feasibility of operating the Umbilical Cord Blood*  
31 *Collection Program as a self-funding program.*

32    (13) *Ensure that California's Umbilical Cord Blood Collection*  
33 *Program does not conflict with other state, national, and*  
34 *international efforts to generate an adequate inventory of,*  
35 *high-quality umbilical cord blood.*

36    (e) *In implementing the program, the department shall make*  
37 *every effort to avoid duplication or conflicts with existing and*  
38 *ongoing programs and to leverage existing resources. The*  
39 *department shall use its existing authority to promote the*  
40 *collection, storage, retrieval, and distribution of umbilical cord*

1 *blood and advise the Legislature of its needs to accomplish these*  
2 *goals.*

3 *(f) (1) All information collected pursuant to the program shall*  
4 *be confidential, and shall be used solely for the purposes of the*  
5 *program. Access to confidential information shall be limited to*  
6 *authorized persons who agree, in writing, to maintain the*  
7 *confidentiality of that information.*

8 *(2) Any person who, in violation of a written agreement to*  
9 *maintain confidentiality, discloses any information provided*  
10 *pursuant to this section, or who uses information provided pursuant*  
11 *to this section in a manner other than as approved pursuant to*  
12 *this section, may be denied further access to any confidential*  
13 *information maintained by the department, and shall be subject*  
14 *to a civil penalty not exceeding one thousand dollars (\$1,000).*  
15 *The penalty provided for in this section shall not be construed as*  
16 *to limit or otherwise restrict any remedy, provisional or otherwise,*  
17 *provided by law for the benefit of the department or any other*  
18 *person covered by this section.*

19 *(3) Notwithstanding the restrictions of this section, an individual*  
20 *to whom the confidential information pertains shall have access*  
21 *to his or her own personal information.*

22 SEC. 3. Section 1627.5 is added to the Health and Safety Code,  
23 to read:

24 1627.5. (a) There shall be established, within the State  
25 Department of Public Health, an implementing committee to  
26 provide guidance and policy suggestions to the department on the  
27 implementation of the Umbilical Cord Blood Collection Program  
28 created pursuant to Section 1627.

29 (b) (1) The implementing committee shall be composed of 15  
30 members. The committee shall include representatives with  
31 expertise and experience in all aspects of umbilical cord collection  
32 and storage. On or before March 1, 2011, the Governor, the Senate  
33 Committee on Rules, and the Speaker of the Assembly shall each  
34 appoint five members of the implementing committee.

35 (2) The implementing committee shall include all of the  
36 following:

37 (A) Two representatives of blood banks licensed or accredited  
38 to provide umbilical cord blood services.

39 (B) A representative of a stem cell transplant center that uses  
40 umbilical cord blood.

1 (C) Two representatives from hospitals providing labor and  
2 delivery services, including one representative from a large hospital  
3 system and one representative from an independent hospital. At  
4 least one representative shall represent a hospital currently  
5 participating in umbilical cord blood collections.

6 (D) Three physicians of different practice types or geographical  
7 regions. One physician shall have expertise in umbilical cord blood  
8 transplantation, one physician shall have expertise in obstetrics or  
9 gynecology, and one shall have expertise in oncology, hematology,  
10 or a pediatric specialty that treats children with anemia, immune  
11 disorders, or cancers that may be treated with stem cell  
12 transplantation.

13 (E) A patient or relative of a patient who has received transplants  
14 using umbilical cord blood.

15 (F) A previous donor of umbilical cord blood or a person who  
16 has searched or has been involved in searching for an unrelated  
17 donor of umbilical cord blood.

18 (G) A person with expertise in typing, matching, and transplant  
19 outcome data analysis.

20 (H) A scientist with expertise in stem cell biology.

21 (I) Two representatives of organizations focusing on medical  
22 conditions that involve umbilical cord blood treatments or ethnic  
23 or racial health disparities.

24 (J) A health plan medical director.

25 (c) Implementing committee members shall serve without  
26 compensation, except that members shall be reimbursed for  
27 authorized travel costs and expenses.

28 (d) For purposes of implementing the program established  
29 pursuant to Section 1627, the implementing committee, by January  
30 1, 2012, shall make initial policy recommendations to the  
31 Legislature, the Assembly and Senate Health Committees, the  
32 Assembly and Senate Judiciary Committees, the Governor, and  
33 the department on meeting the objectives contained in subdivision  
34 (d) of Section 1627.

35 SEC. 4. Section 1627.7 is added to the Health and Safety Code,  
36 to read:

37 1627.7. The department, in consultation with the implementing  
38 committee established pursuant to Section 1627.5, shall submit  
39 two reports to the Assembly and Senate Health Committees, the  
40 Assembly and Senate Judiciary Committees, and the Governor on



1 the effectiveness of the program. The first report shall be submitted  
2 no later than January 1, 2013, and the second report, no later than  
3 January 1, 2018.

4 SEC. 5. Section 1628 of the Health and Safety Code is amended  
5 to read:

6 1628. (a) ~~To the extent public or private funds or grants are~~  
7 ~~identified and secured for these purposes, the Umbilical Cord~~  
8 ~~Blood Collection Program may identify and provide funds for~~  
9 ~~grants or contracts with qualified umbilical cord blood banks,~~  
10 ~~licensed or accredited pursuant to Section 1604.6, for the purposes~~  
11 ~~of collecting and storing genetically diverse umbilical cord blood~~  
12 ~~for public transplantation purposes. The department may accept~~  
13 ~~public and private funds for the purpose of implementing this~~  
14 ~~article.~~

15 (b) ~~No state funds, unless specifically appropriated for this~~  
16 ~~purpose, shall be used for implementation of this section. Any~~  
17 ~~funds made available for purposes of this article shall be deposited~~  
18 ~~into the Umbilical Cord Blood Collection Program Fund, which~~  
19 ~~is hereby created in the General Fund State Treasury. Moneys in~~  
20 ~~the fund shall be available, upon appropriation by the Legislature,~~  
21 ~~for purposes of this article. The~~

22 (c) ~~The fund shall include any federal, state, and private funds~~  
23 ~~made available for purposes of the program, and, notwithstanding~~  
24 ~~Section 16305.7 of the Government Code, any interest earned on~~  
25 ~~moneys in the fund.~~

26 SEC. 6. Section 1630 of the Health and Safety Code is amended  
27 to read:

28 1630. This article shall remain in effect only until January 1,  
29 2015 2020, and as of that date is repealed, unless a later enacted  
30 statute, that is enacted before January 1, 2015 2020, deletes or  
31 extends that date.